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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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WAYNE A. KEOWN
500 WEST CUMMINGS PARK
SUITE 2900
WOBURN, MA 01801

EXAMINER

HELMS, LARRY RONALD

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 04/25/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/779,439

Applicant(s)

NOUJAIM, ANTOINE

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, 4 in part, 5-11, drawn to a method of diagnosing the efficacy of antibody mediated immunotherapy by measuring the level of an antibody that binds to a xenotypic antibody. If Group I is elected claim 4 will be examined to the extent this claim reads on the CA125 antigen, classified in class 435, subclass 7.23.
 - II. Claims 1-3, 4 in part, 5-11, drawn to a method of diagnosing the efficacy of antibody mediated immunotherapy by measuring the level of an antibody that binds to a xenotypic antibody. If Group II is elected claim 4 will be examined to the extent this claim reads on the MUC-1 antigen, classified in class 435, subclass 7.92.
 - III. Claims 1-3, 4 in part, 5-11, drawn to a method of diagnosing the efficacy of antibody mediated immunotherapy by measuring the level of an antibody that binds to a xenotypic antibody. If Group III is elected claim 4 will be examined to the extent this claim reads on the prostate specific antigen. classified in class 435, subclass 7.92.
 - IV. Claims 12-14, 15 in part, 16, drawn to a method of diagnosing the efficacy of antibody mediated immunotherapy by measuring the level of an anti-idiotypic antibody that binds to a xenotypic antibody. If Group IV is elected

claim 15 will be examined to the extent this claim reads on the CA125 antigen, classified in class 435, subclass 7.23.

- V. Claims 12-14, 15 in part, 16, drawn to a method of diagnosing the efficacy of antibody mediated immunotherapy by measuring the level of an anti-idiotypic antibody that binds to a xenotypic antibody. If Group V is elected claim 15 will be examined to the extent this claim reads on the MUC-1 antigen, classified in class 435, subclass 7.92.
- VI. Claims 12-14, 15 in part, 16, drawn to a method of diagnosing the efficacy of antibody mediated immunotherapy by measuring the level of an anti-idiotypic antibody that binds to a xenotypic antibody. If Group VI is elected claim 15 will be examined to the extent this claim reads on the prostate specific antigen, classified in class 435, subclass 7.92.
- VII. Claims 17-20 and 21 in part, drawn to a method of diagnosing the efficacy of antibody mediated immunotherapy by measuring the level of an antibody that binds to the target antigen of a xenotypic antibody. If Group VII is elected claim 21 will be examined to the extent this claim reads on the CA125 antigen, classified in class 435, subclass 7.1.
- VIII. Claims 17-20 and 21 in part, drawn to a method of diagnosing the efficacy of antibody mediated immunotherapy by measuring the level of an antibody that binds to the target antigen of a xenotypic antibody. If Group VIII is elected claim 21 will be examined to the extent this claim reads on the MUC-1 antigen, classified in class 435, subclass 7.1.

- IX. Claims 17-20 and 21 in part, drawn to a method of diagnosing the efficacy of antibody mediated immunotherapy by measuring the level of an antibody that binds to the target antigen of a xenotypic antibody. If Group IX is elected claim 21 will be examined to the extent this claim reads on the prostate specific antigen, classified in class 435, subclass 7.1.
- X. Claims 22-25, drawn to a method of diagnosing the efficacy of antibody mediated immunotherapy by measuring the level of a T cell response, classified in class 435 subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

The methods of Inventions I-X differ in the method objectives, method steps and parameters and in the reagents used. Inventions I-III recite a method of measuring the level of an antibody to different and distinct antigens; Invention IV-VI recite a method of measuring the level of an anti-idiotypic antibody wherein the antibody is directed to different and distinct antigens; Inventions VII-IX recites methods of measuring the level of an antibody that binds to distinct and different antigens, and Invention X recites a method by measuring a T cell response. Methods I-III differ from Groups IV-X in that the method does not require measuring an anti-id response, the method can measure an antibody to the Fc region. Methods VII-IX require measuring an antibody response to an antigen that binds to an antibody in contrast to methods of Group IV-VI which requires measuring an anti-id response. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions I-X are

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separate and distinct in having different method objectives, method steps and parameters and in the reagents used and are patentably distinct.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I: Cancer

Species II: inflammatory disease

Species III bacterial infection

Species IV: parasitic infection

Species V: viral infection

If Groups I-VI are elected then an election of species is required.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-8, 11-13, 16 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D., whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,
Larry R. Helms Ph.D.
703-306-5879

A handwritten signature in black ink, appearing to read 'L. Helms', is positioned to the right of the typed name.